

REMARKS

Favorable reconsideration of the subject application, as amended above, is respectfully requested in view of the comments below.

Claims 25-29, 31-37 and 39-51 are pending in the present application. Claim 25 has been amended to provide the function of the claimed sequences. Support for this amendment is found throughout the specification, for example, the paragraph bridging pages 2 and 3.

Claim 29 has been amended to define the region of the claimed sequence that can be deleted or altered in part as an open reading frame spanning a unique SalI site. This amendment correctly identifies the location within SEQ ID NO:3 of the unique SalI site which is described in the specification. The specification discloses at page 19, line 34 to page 20, line 3 that a non-essential region of the isolated DNA molecule of the present invention was identified using a unique SalI site at nucleotides 28644-28649 of the sequence shown in Figure 1. The unique SalI site (gtcgac) is present in the sequence shown in Figure 1, as indicated in the specification and is located at nucleotides 28673-28678 of SEQ ID NO:3. Thus, it is clear that the open reading described at pages 19-20 of the specification spans nucleotides 28673-28678 of SEQ ID NO:3, as set forth in amended claim 29. Moreover, Figure 7 also shows plasmid OAV600s which has the unique SalI knock out.

Claims 33 and 41 have been amended to recite that the third polynucleotide is inserted into the first or second polynucleotide at a location that is not essential to replication. Support for this amendment is found in Figures 7 and 10. Other

amendments to the claims are made merely to correct grammatical errors or are otherwise non-substantive in nature.

None of the amendments to the claims require further searching on the part of the examiner and are made in compliance with the Examiner's suggestions, in order to place the claims in condition for allowance.

I. Objection to the Declaration

Enclosed herewith is a newly executed declaration that identifies the application by application number and filing date. Accordingly, the objection to the declaration is rendered moot.

II. Objection to Claim 29

It is respectfully submitted that the amendment to claim 29 renders the objection to this claim moot.

III. Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 25, 26, 29, 31-37, 39-47 and 49-51 are rejected under 35 U.S.C. § 112, first paragraph. It is respectfully submitted that the amendments above render each of the grounds of rejection moot.

Claim 41 remains rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was described in the specification in such a way as to enable one of skill in the art to make and/or use the invention. The Examiner asserts that

the specification is enabling for a method of delivering DNA to cultured mammalian cells, but not to a non-mammalian cell, and not to any animal cell *in vivo*.

This rejection is respectfully traversed as follows.

Contrary to the Examiner's assertions, the invention of claim 41 is directed to a method for delivering a DNA molecule to a mammalian cells. There is no recitation in this claim that the method encompasses non-mammalian cells. The Examiner admits that the specification teaches delivery of DNA to cultured mammalian cells, and the previously filed declaration demonstrates delivery of the 45W antigen to sheep *in vivo* via the OAV205 vector, which is described in detail in the specification (See specification at page 21 and Figure 10). The declaration clearly demonstrates that this vector is capable of delivery and expression of an exogenous gene *in vivo*, as required by claim 41. Thus, the invention of claim 41 is enabled.

Accordingly, the rejection of claim 41 under 35 U.S.C. § 112, first paragraph is respectfully traversed.

Claims 42-44 and 47 remain rejected under 35 U.S.C. § 112, first paragraph. The Examiner asserts that the previously filed declaration is insufficient to traverse this rejection because the vectors used in the declaration are not described in the specification. The Examiner also asserts that the specification only teaches use of the claimed vectors as vaccines. The Examiner then asserts that the claims also encompass use of the vectors in gene therapy and or genetic engineering and the declaration does not address these uses.

This rejection is respectfully traversed as follows.

The vector, OAV205, which was used in experiments described in the declaration is described in detail in the specification at page 21 and schematically described in Figure 10. Therefore, the previously filed declaration is sufficient to address the enablement rejection and as such, the Examiner is respectfully requested to reconsider the information and data described therein.

Claims 41-44 and 47 are directed to methods of delivering DNA molecules encoding either a polypeptide or a functional RNA molecule to a mammal. These claims do not require that the DNA/RNA result in a protective immune response. Moreover, the specification teaches that the claimed isolated DNA and its equivalents are useful viral vectors for delivering non-adenoviral DNA to animals (See Abstract, and Technical Field of the Invention (page 1 of the specification)). Thus, the Examiner's comments concerning the disclosed use of the claimed invention is without merit, since the specification directly supports the claims. Moreover, the examples and information in the declaration demonstrate that the claimed method works- DNA is delivered to a mammalian cell *in vitro* or *in vivo* and expressed therein.

The Examiner's comment that the declaration is not commensurate in scope with the claims is not understood. As discussed above, the claims are directed to methods of delivering DNA to a mammalian cell and the declaration clearly demonstrates this. It is not necessary that any other embodiment of the invention (such as gene therapy or vaccine use) be demonstrated in the declaration or elsewhere to provide a sufficient enabling disclosure for claims 41-44 and 47.

Accordingly, the rejection of claims 41-44 and 47 under 35 usc 112, first paragraph is respectfully traversed.

IV. Rejection of Claims Under 35 U.S.C. § 112, second Paragraph

Claims 27, 29 and 47 stand rejected under 35 U.S.C. § 112, second paragraph, for failing to point out and distinctly claim the subject matter which applicant regards as the invention.

It is respectfully submitted that the amended language of claims 27 and 29 provides proper antecedent basis; and the typographical error of claim 47 has been corrected.

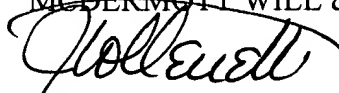
Accordingly, the rejection of these claims is respectfully traversed.

It is respectfully submitted that the present application, as amended above, is in condition for allowance, an early notification thereof being earnestly solicited. To the extent necessary, a petition for an extension under 37 C.F.R. § 1.136 is hereby made. Please charge any shortage in fees in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417, and please credit any excess fees to such account.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

MCDERMOTT WILL & EMERY LLP

A handwritten signature in black ink, appearing to read 'J. Toffenetti', written over the printed name.

Judith L. Toffenetti
Registration No. 39,048

600 13th Street, N.W.
Washington, DC 20005-3096
(202) 756-8000 JLT:ajb
Facsimile: (202) 756-8087
Date: June 30, 2004



Docket No.: 64162-022

DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that:

My residence, post office and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter claimed and for which a patent is sought on the invention entitled **DNA ENCODING OVINE ADENOVIRUS (OAV287) AND ITS USE AS A VIRAL VECTOR**, the specification of which

☐ is attached hereto.

☒ was filed on December 16, 1999 as Application Serial No. 09/464,767 and was amended by the Preliminary Amendment filed December 16, 1999.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is known to me to be material to patentability in accordance with Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Applications(s):

Number	Country	Day/Month/Year filed	Priority Claimed
PM7101	Australia	July 26, 1994	X
PCT/AU95/00453	International	July 26, 1995	X

I hereby claim the benefit under 35 USC §119(e) of any United States provisional application(s) listed below.

Prior Provisional Application(s):

Application Number	Filing Date
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I hereby claim the benefit under Title 35, United States Code, Section 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, Section 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, Section 1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Prior U.S. Application(s):

Serial No.	Filing Date	Status: Patented, Pending, Abandoned
08/776,274	January 24, 1997	Abandoned

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

I hereby appoint the following attorney(s) and/or agent(s): Stephen A. Becker, Reg. No. 26,527; John G. Bisbikis, Reg. No. 37,095; Richard E. Brown, Reg. No. 47,453; Daniel Bucca, Reg. No. 42,368; Kenneth L. Cage, Reg. No. 26,151; Alex H. Chan, Reg. No. 52,713; Bernard P. Codd, Reg. No. 46,429; Lawrence T. Cullen, Reg. No. 44,489; Paul Devinsky, Reg. No. 28,553; Margaret M. Duncan, Reg. No. 30,879; Ramyar M. Farid, Reg. No. 46,692; Michael E. Fogarty, Reg. No. 36,139; John R. Fuisz, Reg. No. 37,327; Keith E. George, Reg. No. 34,111; Thomas A. Haag, Reg. No. 47,621; John A. Hankins, Reg. No. 32,029; Catherine Krupka, Reg. No. 46,227; Jack Q. Lever, Reg. No. 28,149; Michael A. Messina, Reg. No. 33,424; Dawn L. Palmer, Reg. No. 41,238; Joseph H. Paquin, Jr., Reg. No. 31,647; Scott D. Paul, Reg. No. 42,984; William D. Pegg, Reg. No. 42,988; Gene Z. Robinson, Reg. No. 33,351; Brian K. Seidleck, Reg. No. 51,321; Joy Ann G. Serauskas, Reg. No. 27,952; David A. Spenard, Reg. No. 37,449; Arthur J. Steiner, Reg. No. 26,106; David M. Tennant, Reg. No. 48,362; Judith L. Toffenetti, Reg. No. 39,048; Kelli N. Watson, Reg. No. 47,170; Cameron K. Weiffenbach, Reg. No. 44,488; Aaron Weisstuch, Reg. No. 41,557; Edward J. Wise, Reg. No. 34,523; Jeffrey A. Woller, Reg. No. 48,041; Alexander V. Yampolsky, Reg. No. 36,324; William Young, Reg. No. 54,718; and Wei-Chen Chen and Tomoki Tanida, admitted under 37 CFR 10.9(b) all of

McDERMOTT, WILL & EMERY
600 13th Street, N.W.
Washington, D. C. 20005-3096

Direct Telephone Calls to: Telephone (202) 756-8000

with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith, and all future correspondence should be addressed to them.

Full name of sole or first inventor: Gerald Wayne Both

Inventor's signature: *G.W. Both*

Date: 18/5/04

Residence: North Ryde, Australia

Citizenship: Australian

Post Office Address: 4 Leslie Street, North Ryde, NSW 2113 AUSTRALIA

Full name of second inventor: David Bernard Boyle

Inventor's signature: *DB Boyle*

Date: 24/5/04

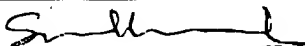
Residence: Leopold, Australia

Citizenship: Australian

Post Office Address: 6 Mary Place, Leopold, VIC 3224 AUSTRALIA

Full name of third inventor: ^uSadhanshu Vrat

x Inventor's signature:



Date: 3 June 2004

Residence: New Dehli, India

Citizenship: Indian

Post Office Address: National Institute of Immunology, JNU Campus, New Dehli 110
067 India